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TAKEDA SAN DIEGO, INC. 10410 SCIENCE CENTER DRIVE SAN DIEGO, CA 92121			EXAMINER STEADMAN, DAVID J	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/826,170	Applicant(s) CRONIN ET AL.	
	Examiner David J. Steadman	Art Unit 1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 September 2007 and 09 December 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 7,8,10,25,26,28,31,44-46 and 49-53 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 7,8,10,25,26,28,31,44-46 and 49-53 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of the Application

[1] Claims 7-8, 10, 25-26, 28, 31, 44-46, and 49-53 are pending in the application.

[2] Applicant's amendment to the claims, filed on 12/9/07, is acknowledged. Claims 7-8, 25-26, 44, and 46 have been amended and claim 53 is newly added. This listing of the claims replaces all prior versions and listings of the claims.

[3] Applicant's remarks filed on 9/3/07 and 12/9/07 in response to the Office communications filed on 5/4/07 and 11/9/07, respectively, are acknowledged.

Applicant's arguments have been fully considered and are deemed to be persuasive to overcome some of the rejections and/or objections previously applied. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.

[4] The text of those sections of Title 35 U.S. Code not included in the instant action can be found in a prior Office action.

Specification/Informalities

[5] The objection to the specification as being inconsistent in identifying the amino acid sequence of the atomic coordinate listing of Figure 3 as SEQ ID NO:5 is maintained for the reasons of record and the reasons set forth below. The objection was fully explained in a previous Office action. See particularly paragraph 8 of the Office action filed on 5/4/07.

RESPONSE TO ARGUMENT: At p. 5 of the remarks filed on 9/3/07, applicant argues the first amino acid of the Figure 3 structural coordinates is Gly, which is the

12th amino acid of SEQ ID NO:5 and thus, according to applicant, the sequence of the Figure 3 structural coordinates "accurately represents the atomic coordinate listing of the amino acid sequences set forth in SEQ ID NO:5".

Applicant's argument is not found persuasive. Applicant's admission that the sequence of the Figure 3 structural coordinates is a *subsequence* of SEQ ID NO:5 is evidence that they are not the same, *i.e.*, the sequence of SEQ ID NO:5 is not the same as the sequence of the Figure 3 structural coordinates. *If* the sequence of the Figure 3 structural coordinates is an *identical subsequence* of SEQ ID NO:5, it is suggested that applicant identify in Figure 3 the contiguous amino acid subsequence of SEQ ID NO:5, that is shown in the sequence of the Figure 3 structural coordinates, *e.g.*, "Amino acids X to Y of SEQ ID NO:5".

[6] The objection to the specification as introducing new matter by changing the range of amino acids for which structure coordinates are not reported from 1-12 to 1-11 for chain A is withdrawn in view of applicant's clarifying remarks at p. 6, top of the remarks filed on 9/3/07.

Claim Objection

[7] Claim 25 is objected to in the recitation of "wherein the protein crystal has a crystal lattice... $\alpha=\beta=\gamma=90^\circ$ " prior to the step of "storing the crystallization volume..." and in order to substantially improve claim form, it is suggested that the phrase "wherein the protein crystal has a crystal lattice... $\alpha=\beta=\gamma=90^\circ$ " be placed *after* the "storing the crystallization...of the protein" step.

[8] Claim 45 is objected to in the recitation of “an entity” and in order to substantially improve claim form and maintain consistency with claims 49-52, it is suggested that the noted phrase be amended to recite “one or more entities”.

[9] Claim 49 is objected to in the recitation of “selecting one or more entities...and contacting the selected entities...” In order to improve claim form, it is suggested that applicant amend the noted phrase to recite, “selecting one or more entities...and contacting the selected one or more entities...”

Claim Rejections - 35 USC § 112, First Paragraph

[10] The new matter rejection of claim(s) 8, 10, 26, 28, and 46 are rejected under 35 U.S.C. 112, first paragraph, is maintained for the reasons of record and the reasons stated below. The rejection was fully explained in a prior Office action. See particularly paragraph 11 of the Office action filed on 5/4/07 and paragraph 10 of the Office action filed on 9/5/06.

RESPONSE TO ARGUMENT: Regarding claims 8, 26, and 46 reciting the limitation “crystal unit cell comprises three protein molecules”, applicant argues (remarks filed on 9/3/07 at p. 7), “Support for the amendment is present at [0118] of the Specification, which recites that the asymmetric unit cell comprises three protein molecules in a complex”.

Applicant’s argument is not found persuasive. The examiner maintains the position that the noted limitations introduce new matter into the claims. The relevant portion of paragraph 118 that applicant relies on for descriptive support of the noted

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limitation appears to be "...it was realized that the *asymmetric unit* comprised three HDAC-2-Zn²⁺-TSA molecules" (emphasis added), which does not appear to support the limitation of "unit cell comprises three protein molecules", particularly as a skilled artisan in the field of protein crystallography recognizes that the asymmetric unit and the unit cell are not necessarily one and the same. See, e.g., "Developing using Crystallographic Maps" at

www.ysbl.york.ac.uk/~cowtan/clipper/doc/p_develop_map.html, last viewed on 1/6/08.

Applicant is invited to show support for the limitation at issue.

Regarding claims 10 and 28 reciting the limitation "a resolution of a value equal to or less than 3.0 Angstroms", applicant argues, "Paragraphs [0147] and [0192] of the Specification as originally filed, provide support for the above limitation. Paragraph [0147] states that 'the root mean square deviation of alpha-carbon atoms or non-hydrogen atoms may optionally be less than 2.7 Å, 2.5 Å, 2.0 Å, 1.5 Å, 1 Å, 0.5 Å, or less,' and paragraph [0192] states that the structure coordinates of the protein complexes may be refined versus 1.5-3Å resolution X-ray data".

Applicant's argument is not found persuasive. The disclosure of paragraph 147 of the specification is related to calculating a root mean square deviation between structural coordinates, which is unrelated to x-ray diffraction resolution, and fails to mention a range including a 3.0 Angstrom resolution. Moreover, the disclosure of the range of 1.5-3 Angstroms in paragraph 192 would not appear to support an "at least" limitation, particularly in view of the Court's holding in *In re Wertheim*, 541 F.2d 257, 191 USPQ 90 (CCPA 1976).

Applicant is invited to show support for the limitations at issue.

[11] The written description and scope of enablement rejections of claim 44 under 35 U.S.C. 112, first paragraph, is withdrawn in view of the amendment to the claims, limiting the recited polypeptide to being “non-crystalline”.

In analyzing the specification’s descriptive support for the limitation of “non-crystalline”, it is noted that according to MPEP 2173.05(i), “Any negative limitation or exclusionary proviso must have basis in the original disclosure. If alternative elements are positively recited in the specification, they may be explicitly excluded in the claims. See *In re Johnson*, 558 F.2d 1008, 1019, 194 USPQ 187, 196 (CCPA 1977)”. See also the Court’s holding in *Ex parte Parks*, 30 USPQ2d 1234 (Bd. Pat. App. & Int. 1993), “[i]n rejecting a claim under the first paragraph of 35 U.S.C. 112 for lack of adequate descriptive support, it is incumbent upon the examiner to establish that the originally-filed disclosure would not have reasonably conveyed to one having ordinary skill in the art that an appellant had possession of the now claimed subject matter. *Wang Laboratories, Inc. v. Toshiba Corp.*, 993 F.2d 858, 26 USPQ2d 1767 (Fed.Cir. 1993). Adequate description under the first paragraph of 35 U.S.C. 112 does not require *literal* support for the claimed invention. *In re Herschler*, 591 F.2d 693, 200 USPQ 711 (CCPA 1979); *In re Edwards*, 568 F.2d 1349, 196 USPQ 465 (CCPA 1978; *In re Wertheim*, 541 F.2d 257, 191 USPQ 90 (CCPA 1976). Rather, it is sufficient if the originally-filed disclosure would have conveyed to one having ordinary skill in the art that an appellant

had possession of the concept of what is claimed. *In re Anderson*, 471 F.2d 1237, 176 USPQ 331 (CCPA 1973).”

In this case, while there does not appear to be *in haec verba* support for the limitation of “non-crystalline” in the specification, it is noted that the specification throughout positively recites “crystal” or “crystalline” polypeptides as encompassed by the claims and further, the specification throughout contemplates the polypeptides encompassed by the claims in a non-crystalline form, *i.e.*, in soluble form. Moreover, one of skill in the art would recognize that in order to crystallize the polypeptides, one must necessarily first produce them in a soluble or non-crystalline form. As such, it is the examiner’s position that the limitation of “non-crystalline” finds adequate descriptive support in the original application as filed.

[12] The written description rejection of claim(s) 7-8, 10, 25-26, 28, 31, 45-46, and 49-52 under 35 U.S.C. 112, first paragraph, is maintained for the reasons of record and the reasons stated below. The rejection was fully explained in a prior Office action. See particularly paragraph 12 beginning at p. 5 of the Office action filed on 5/4/07.

RESPONSE TO ARGUMENT: Beginning at p. 8, top of the remarks filed on 9/3/07, applicant argues the rejection is obviated by claim amendment “to clarify the scope of the claims”, apparently to limit the claims to recite, “wherein said protein forms a complex with an inhibitor ligand”.

Applicant’s argument is not found persuasive. The examiner acknowledges the amendment to claims 7 and 25 to limit the genus of proteins of the crystalline form to

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being able to form a complex with an inhibitor ligand. It is noted that: 1) the term “protein forms a complex with an inhibitor ligand” has been interpreted as meaning that the protein has the ability to form a complex, and does not require the protein to *actively be in complex* with “an inhibitor ligand” and 2) the structure of the “inhibitor ligand” is completely undefined and unlimited. Consequently, the genus of crystals is seen as encompassing widely variant species, encompassing a crystal of a protein, either alone or in complex with any “inhibitor ligand” having any structure. In this case, the specification discloses only a single disclosed species of crystals, *i.e.*, a crystal of purified SEQ ID NO:5 in complex with TSA and Zn^{++} having the space group symmetry $P2_12_12_1$ and having vector lengths $a=92.1 \text{ \AA}$, $b=97.6 \text{ \AA}$, and $c=138.9 \text{ \AA}$ and $\alpha=\beta=\gamma=90^\circ$ that diffracts x-rays to a resolution of 1.84 \AA and has three molecules of SEQ ID NO:5 in complex with TSA and Zn^{++} per asymmetric unit; the specification discloses only a single representative species of the genus of crystallization methods, *i.e.*, the method disclosed at p. 52 of the specification; the specification discloses only a single representative species of crystal structures of SEQ ID NO:5, *i.e.*, the 3-D structure of SEQ ID NO:5 having the structural coordinates of Figure 3; the specification discloses only a single representative species of methods of “rational drug design,” *i.e.*, using the structure of SEQ ID NO:5 having the structural coordinates of Figure 3 to perform a fitting operation between an entity and the computer model and analyzing the results of the fitting operation to quantify the association between the entity and the model; and discloses only a single representative species of activities of the protein or a cell expressing the protein that can be measured, *i.e.*, histone deacetylase activity. While

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applicant may argue that a skilled artisan would reasonably expect that co-crystallizing the recited protein in complex with any other "inhibitor ligand" under the disclosed conditions would result in a crystal as encompassed by the claims, there is no evidence of record to support this position and the state of the art at the time of the invention would suggest otherwise. For example, a common method of obtaining a crystal with a ligand other than that of an initial crystal is to soak a crystal of a liganded protein with a different ligand. However, in view of the state of the art at the time of the invention, it appears there was no way to predict *a priori* whether the resulting crystal will maintain the space group and unit cell dimensions of the parent crystal. See, *e.g.*, Skarzynski et al. (*Acta Crystallogr D Biol Crystallogr* D62:102-107, 2006), which discloses, "crystals of complexes obtained by compound soaking may become damaged, change their diffraction properties or even change the space group during the soaking experiment" (p. 103, column 2, middle).

Other than the single species as noted above, the specification fails to describe any other compositions or crystals or methods for crystallization thereof as encompassed by the claims. At the time of the invention, the prior art acknowledged a high level of unpredictability with respect to protein crystallography as evidenced by Branden, Drenth, Kierzek, and Wiencek (cited in prior Office actions). MPEP § 2163 states "[f]or inventions in an unpredictable art, adequate written description of a genus which embraces widely variant species cannot be achieved by disclosing only one species within the genus." As such, the single disclosed species of compositions and crystals and methods for making said crystal as noted above fail to adequately describe

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all compositions, crystals, and methods as encompassed by the claims. Given the lack of description of a representative number of species, the specification fails to sufficiently describe the claimed invention in such full, clear, concise, and exact terms that a skilled artisan would recognize that applicant was in possession of the claimed invention.

At least for the reasons of record and reasons stated herein, it is the examiner's position that the specification fails to adequately describe the claimed invention.

[13] The scope of enablement rejection of claim(s) 7-8, 10, 25-26, 28, 31, 45-46, and 49-52 under 35 U.S.C. 112, first paragraph, is maintained for the reasons of record and the reasons stated below. The rejection was fully explained in a prior Office action. See particularly paragraph 13 beginning at p. 8 of the Office action filed on 5/4/07.

RESPONSE TO ARGUMENT: Beginning at p. 8, top of the remarks filed on 9/3/07, applicant argues the rejection is obviated by claim amendment "to clarify the scope of the claims", apparently to limit the claims to recite, "wherein said protein forms a complex with an inhibitor ligand".

Applicant's argument is not found persuasive. The examiner acknowledges the amendment to claims 7 and 25 to limit the genus of proteins of the crystalline form to being able to form a complex with an inhibitor ligand. It is noted that: 1) the term "protein forms a complex with an inhibitor ligand" has been interpreted as meaning that the protein has the ability to form a complex, and does not require the protein to *actively be in complex* with "an inhibitor ligand" and 2) the structure of the "inhibitor ligand" is completely undefined and unlimited. Consequently, the scope of recited crystals

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encompasses crystals of a protein alone or optionally in complex with *any* “inhibitor ligand” having any structure. As noted in a prior Office action, the specification discloses only a single working example of a crystal as encompassed by the claims, *i.e.*, a crystal of purified SEQ ID NO:5 in complex with TSA and Zn⁺⁺ having the space group symmetry P2₁2₁2₁ and having vector lengths a=92.1 Å, b=97.6 Å, and c=138.9 Å and $\alpha=\beta=\gamma=90^\circ$ that diffracts x-rays to a resolution of 1.84 Å and has three molecules of SEQ ID NO:5 in complex with TSA and Zn⁺⁺ per asymmetric unit; the specification discloses only a single representative species of the genus of crystallization methods, *i.e.*, the method disclosed at p. 52 of the specification; the specification discloses only a single representative species of crystal structures of SEQ ID NO:5, *i.e.*, the 3-D structure of SEQ ID NO:5 having the structural coordinates of Figure 3; the specification discloses only a single representative species of methods of “rational drug design,” *i.e.*, using the structure of SEQ ID NO:5 having the structural coordinates of Figure 3 to perform a fitting operation between an entity and the computer model and analyzing the results of the fitting operation to quantify the association between the entity and the model; and discloses only a single representative species of activities of the protein or a cell expressing the protein that can be measured, *i.e.*, histone deacetylase activity. Other than this single working example, the specification fails to provide any specific guidance for crystallizing SEQ ID NO:5 alone or optionally in complex with any other ligand besides TSA and Zn⁺⁺ with an expectation of achieving a diffraction-quality crystal that maintains the recited space group and unit cell dimensions, particularly in view of the high level of unpredictability with respect to the art of protein crystallography

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as evidenced by Branden, Drenth, Kierzek, and Wiencek (cited in prior Office actions). While applicant may argue that a skilled artisan would expect that co-crystallizing the recited protein in complex with any other “inhibitor ligand” under the disclosed conditions would result in a crystal as encompassed by the claims, there is no evidence of record to support this position and the state of the art at the time of the invention would suggest otherwise. For example, a common method of obtaining a crystal with a ligand other than that of an initial crystal is to soak a crystal of a liganded protein with a different ligand. However, as noted above, there is no way to predict *a priori* whether the resulting crystal will maintain the space group and unit cell dimensions of the parent crystal prior to ligand soaking. See the cited teachings of Skarzynski as set forth above.

In view of the broad scope of the claims, the lack of guidance and working examples provided in the specification, the high level of unpredictability as evidenced by the prior art, and the amount of experimentation required to make all crystals and polypeptides as broadly encompassed by the claims, undue experimentation would be necessary for a skilled artisan to make and use the entire scope of the claimed invention.

Applicant has not provided sufficient guidance to enable one of ordinary skill in the art to make and use the claimed invention in a manner reasonably correlated with the scope of the claims. The scope of the claims must bear a reasonable correlation with the scope of enablement (*In re Fisher*, 166 USPQ 19 24 (CCPA 1970)). Without sufficient guidance, determination of having the desired biological characteristics is unpredictable and the experimentation left to those skilled in the art is unnecessarily,

and improperly, extensive and undue. See *In re Wands* 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988).

Claim Rejections - 35 USC § 102

[14] The rejection of claim 44 under 35 U.S.C. 102(e) as being anticipated by Bressi et al. (US Patent 7,169,801) is maintained for the reasons of record and the reasons set forth below. The rejection was fully explained in a prior Office action. See particularly paragraph 15 beginning at p. 14 of the Office action filed on 5/4/07. Claim 53 is included in the instant rejection because the polypeptide of Bressi is disclosed as being isolated (Bressi, column 91, lines 55-60 and column 92, lines 50-62). Thus, claims 44 and 53 are rejected herein.

RESPONSE TO ARGUMENT: At p. 8 of the remarks filed on 9/3/07 applicant argues the HDAC-2 of Bressi has an additional MGS tripeptide at the N-terminus and thus does not *consist of* SEQ ID NO:5 as required by the claims.

Applicant's argument is not found persuasive. It appears that applicant is comparing the polypeptide of SEQ ID NO:3 of Bressi with SEQ ID NO:5 herein. However, applicant fails to acknowledge that SEQ ID NO:3 of Bressi was further treated with trypsin (column 92, lines 50-62) and there is no evidence of record that SEQ ID NO:3 of Bressi – *after* treatment with trypsin – is distinct from SEQ ID 5 herein. "The arguments of counsel cannot take the place of evidence in the record. *In re Schulze*, 346 F.2d 600, 602, 145 USPQ 716, 718 (CCPA 1965)". See MPEP 716.01(c).II.

According to MPEP 2112.01, "Where the claimed and prior art products...are produced by identical or substantially identical processes, a *prima facie* case of either anticipation or obviousness has been established". Based upon a comparison of the disclosure of the method of making SEQ ID NO:5 herein at specification pp. 51-52, Example 2 with the method of making the polypeptide of Bressi (column 91, lines 55-60 and column 92, lines 50-62), it appears that the methods are essentially identical. In the absence of "evidence showing that the prior art products do not necessarily possess the characteristics of the claimed product" (MPEP 2112.01), the examiner maintains that the polypeptide of Bressi is the same as the polypeptide of claims 44 and 53 herein.

Claim Rejections - 35 USC § 101

[15] The rejection of claim 44 under 35 U.S.C. 101 as being directed to non-statutory subject matter is maintained for the reasons of record and the reasons stated below. The rejection was fully explained in a prior Office action. See particularly paragraph 16 beginning at p. 15 of the 5/4/07 Office action.

RESPONSE TO ARGUMENT: At p. 9 of the remarks filed on 9/3/07 applicant argues that since the TPCK-trypsin used to cleave SEQ ID NO:1 has been chemically treated to inhibit chymotrypsin, this is indicative of the "hand of man".

Applicant's argument is not found persuasive. That TPCK-trypsin has a reduced level of chymotrypsin would appear to be irrelevant to the determination of whether or not naturally-occurring trypsin would cleave SEQ ID NO:1 to produce SEQ ID NO:5. Here, there is no evidence of record or line of reasoning that would support the position

that TPCK-trypsin cleavage site specificity is any different from that of naturally-occurring trypsin. Moreover, there is no evidence of record or line of reasoning that would support the position that the presence of chymotrypsin alters the cleavage site specificity of naturally-occurring trypsin. Thus, a skilled artisan would recognize and fully expect that naturally-occurring trypsin would cleave SEQ ID NO:1 to yield the polypeptide of SEQ ID NO:5 in its naturally-occurring milieu.

Claim Rejections – Double Patenting

[16] The provisional obviousness-type double patenting rejection of claims 45-46 as being unpatentable over claims 22-31 and 42-51 of co-pending Application No. 10/826,134 is maintained for the reasons of record.

At p. 9 of the remarks filed on 9/3/07 applicant argues the rejection is moot since claims 45-46 are withdrawn. However, this is not found persuasive as claims 45-46 have not been withdrawn by the examiner and are not indicated as being withdrawn in the claims filed on 12/9/07. As such, the provisional rejection is maintained.

Conclusion

[17] Status of the claims:

Claims 7-8, 10, 25-26, 28, 31, 44-46, and 49-53 are pending.

Claims 7-8, 10, 25-26, 28, 31, 44-46, and 49-53 are rejected.

No claim is in condition for allowance.

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THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David J. Steadman whose telephone number is 571-272-0942. The examiner can normally be reached on Mon to Fri, 7:30 am to 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Kerr Bragdon can be reached on 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/David J. Steadman/
David J. Steadman, Ph.D.
Primary Examiner
Art Unit 1656